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**From:** Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]  
**Sent:** 11/3/2016 2:48:45 PM  
**To:** Kish, Tony [Kish.Tony@epa.gov]; Roe, Lindsay [Roe.Lindsay@epa.gov]  
**Subject:** RE: Chlormequat chloride- ACN waiver

We will discuss at PRIA meeting today.

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**From:** Kish, Tony  
**Sent:** Thursday, November 03, 2016 10:46 AM  
**To:** Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>  
**Subject:** FW: Chlormequat chloride- ACN waiver

I don't see any issues with Taminco submitting the ACN Jan 2017 as a resub w/o extra PRIA fee and sending it to HED for incorporation into import tolerance RA. We would tell them if it comes much later, it may be best to hold and submit with the section 3.

What do you think?

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**From:** Davis, Donna  
**Sent:** Thursday, November 03, 2016 10:35 AM  
**To:** Roe, Lindsay <Roe.Lindsay@epa.gov>; Kish, Tony <Kish.Tony@epa.gov>; Craig, Evisabel <Craig.Evisabel@epa.gov>  
**Subject:** FW: Chlormequat chloride- ACN waiver

This is what comes from me rushing through emails. Thanks to Evisabel for the clarification. Yes, if the ACN comes in Jan, we could make a November LSDD and incorporate the study.

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**From:** Craig, Evisabel  
**Sent:** Thursday, November 03, 2016 7:52 AM  
**To:** Davis, Donna <Davis.Donna@epa.gov>  
**Subject:** RE: Chlormequat chloride- ACN waiver

Donna,

I think Tony's proposal makes sense. If the registrant submits the ACN in January 2017 and the LSDD is November 2017, we should have enough time to review that study and incorporate it into the risk assessment (about 6 months).

Evisabel

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**From:** Davis, Donna  
**Sent:** Thursday, November 03, 2016 6:11 AM  
**To:** Kish, Tony <Kish.Tony@epa.gov>  
**Cc:** Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Craig, Evisabel <Craig.Evisabel@epa.gov>  
**Subject:** RE: Chlormequat chloride- ACN waiver

Tony,

Sorry for the confusion. HASPOC does not have the last say on a 90-day screen. The team and Dana have the last say. I reconfirmed with Dana yesterday that we are fine with moving the action into review. The HASPOC should only confirm that the ACN is required, but it's the team and Dana's call if that is a show stopper and we do not believe that it is, given

that the registrant has committed to do the study. So from an HED perspective, this passes the screen and should be put into full review.

With respect to the ACN, I cannot guarantee a May delivery for a RA which includes a full review of that study and incorporation of that study into the RA. If the study shows no effects that impact the endpoints, we could use it, but if the study shows that there are effects, and that study should be part of the RA, then we would need an extension of the PRIA deadline to fully incorporate it. Our plan now would be to apply a 10X for a missing study for this action. That said, we may or may not be able to make the safety finding with the 10X – depending on how refined EFED can get the water numbers.

If you want to sit down and talk we can do that.

Donna

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**From:** Kish, Tony

**Sent:** Wednesday, November 02, 2016 5:06 PM

**To:** Davis, Donna <[Davis.Donna@epa.gov](mailto:Davis.Donna@epa.gov)>

**Cc:** Giles-Parker, Cynthia <[Giles-Parker.Cynthia@epa.gov](mailto:Giles-Parker.Cynthia@epa.gov)>; Roe, Lindsay <[Roe.Lindsay@epa.gov](mailto:Roe.Lindsay@epa.gov)>

**Subject:** Chlormequat chloride- ACN waiver

Donna- we're confused. Per HEDs last email, the HED 90 day screen which stated the ACN is a "data gap" has been revised to indicate there is no ACN data gap, but we understand HASPOC denied the ACN waiver partly because it's a required study?

While we're wtg for the final HASPOC memo, we spoke with Taminco today who advises they can submit the ACN in early Jan 2017. The import tolerance LSDD is 11/11/17 and the PRIA is 5/10/18 so if the ACN gets to HED in feb 2017 does that give HED time to review it for the import tolerance?

The attached meeting minutes indicate we would grant an ACN waiver for the import tolerance action if they committed in writing to doing the study which they did and HED reviewed. Our understanding is HASPOC is not granting the waiver. Taminco is asking why we changed our mind about the waiver? Maybe we're not understanding this correctly.

Thanks, Tony

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**From:** McLaughlin, Jessica J [<mailto:jessicamclaughlin@eastman.com>]

**Sent:** Wednesday, November 02, 2016 4:34 PM

**To:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>; Roe, Lindsay <[Roe.Lindsay@epa.gov](mailto:Roe.Lindsay@epa.gov)>

**Cc:** Hott, John L <[johnhott@eastman.com](mailto:johnhott@eastman.com)>

**Subject:** FW: Meeting Minutes from July 14, 2016 Meeting Between EPA and Eastman/Taminco

Hello,

Thanks again for meeting with us. I am forwarding you the meeting minutes that I prepared following our pre-submission meeting for chlormequat chloride on July 14<sup>th</sup>. Also, the FIFRA Statute that John was speaking to during our call is:

Preliminary Technical Screen As Written in the FIFRA Statute

FIFRA section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings" directs the Agency to conduct a preliminary technical screen of the application. Screening is conducted no later than 90 days after the PRIA start. In conducting this technical screen, the Agency determines whether:

(1) the application and data are accurate and complete;

- (2) the application and data are consistent with the proposed labeling and any proposed tolerance or tolerance exemption; and
- (3) the application and data are such that subject to full review could result in the granting of the application.

We are hopeful that the information we provided as part of our Import Tolerance petition, in addition to the information we provided during our call today, will satisfy the preliminary technical screen. I look forward to hearing from you soon.

Regards,  
Jessica McLaughlin

North American Crop Protection Steward  
Product Stewardship and Regulatory Affairs  
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**From:** McLaughlin, Jessica J  
**Sent:** Friday, July 29, 2016 4:10 PM  
**To:** 'Kish, Tony'  
**Cc:** Roe, Lindsay; Kasprzyk, Kiryssa  
**Subject:** Meeting Minutes from July 14, 2016 Meeting Between EPA and Eastman/Taminco

Hello Tony,

I have attached the meeting minutes from our meeting on July 14, 2016 where we discussed data requirements for a Section 3 registration of chlormequat chloride for food use. I appreciate your willingness to meet with us and allow us to get a better understanding of how to move forward with this project. Please let me know if you have any questions or comments.

Regards,  
Jessica McLaughlin

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